

NO. 13-16833

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF
AMERICA, ET AL.,
v.
ALAMEDA COUNTY, ET AL.

On Appeal from the United States District Court
for the Northern District of California

Honorable Richard Seeborg

No. C 12-6203 RS

BRIEF OF *AMICUS CURIAE*
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IN SUPPORT OF APPELLEES

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**IDENTITY, INTEREST AND SOURCE OF AUTHORITY FOR
*AMICUS CURIAE***

California Attorney General Kamala D. Harris respectfully submits this amicus curiae brief pursuant to Federal Rule of Appellate Procedure 29(a) and in support of Defendants-Appellees Alameda County, *et al.*

(“Alameda”). The Attorney General submits this brief in her capacity as the chief law enforcement officer of the State of California and pursuant to her responsibility to protect the environment and natural resources of California for the benefit of the People. Cal. Const., art. V, § 13; Cal. Gov’t Code §§ 12600-12612.

At issue in this case is whether Alameda’s Safe Drug Disposal Ordinance (“Ordinance”) – an example of an extended producer responsibility (“EPR”) program requiring manufacturers to take responsibility for waste resulting from their products – runs afoul of the dormant Commerce Clause. As set out in Alameda’s brief and below, it does not.

The Attorney General has a strong interest in ensuring that the dormant Commerce Clause continues to be interpreted in a way that preserves the abilities of state and local governments to adopt innovative programs to

address threats to public health and welfare and the environment – programs like Alameda’s Ordinance.

EPR programs are an important part of California’s strategy for keeping harmful chemicals out of the State’s landfills, water supplies, and households. These programs internalize “the costs of product collection, recycling, and disposal into the total product costs” while reducing risks to human health and the environment. *See* 2008 Cal. Stat. 3. In the last six years, the Legislature has enacted statewide EPR programs for several different products, including pesticide containers (Cal. Food & Agric. Code § 12841.4); mercury thermostats (Cal. Health & Safety Code § 25214.8.10, *et seq.*); architectural paint (Cal. Pub. Res. Code § 48700, *et seq.*); carpet (*id.* § 42970, *et seq.*); and mattresses (*id.* § 42985, *et seq.*). California is also just beginning to implement its Safer Consumer Products law which will eventually require manufacturers of certain products to establish and maintain end-of-life management programs that include comprehensive product stewardship plans. Cal. Health & Saf. Code § 25253(b)(7); Cal. Code Regs., tit. 22, § 69506.7(a), (c).

California’s EPR programs have been successful. For example, in its first 8.5 months, California’s EPR program for paint collected and processed more than 600,000 gallons of post-consumer paint, 96 percent of which was

recycled or used for a beneficial purpose.¹ In 2012, California's EPR program for mercury recovered and properly disposed of 219 pounds² of mercury, keeping it out of the regular waste stream.³ State and local governments must continue to have the flexibility and discretion to adopt innovative regulations, such as EPR programs, to dispose of environmentally harmful waste safely, efficiently, and cost-effectively.

More generally, the Attorney General has a strong interest in the correct and consistent application of the dormant Commerce Clause. An unwarranted expansion of this doctrine would have adverse implications for a wide variety of state laws and regulations that touch interstate commerce. Recently, a number of California's laws have been challenged under this doctrine, including California's greenhouse-gas-reducing fuels regulation and its ban on the sale of shark fins.⁴ The balance struck in the existing

¹ *California Paint Stewardship Program: Year 1 Annual Report*, available at <http://www.paintcare.org/docs/ca-annual-report-year-1.pdf>.

² 219 pounds is almost 100 kilograms. To place this figure in context, solid waste containing as little as 20 milligrams of mercury per kilogram is considered hazardous. Cal. Code Regs., tit. 40, § 261.24(a)(2)(A).

³ *CA DTSC Thermostat Collection Report for Calendar Year 2012 Activities*, available at http://www.dtsc.ca.gov/HazardousWaste/upload/2012_-AR_-CA.pdf

⁴ See *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070 (9th Cir. 2013); *Chinatown Neighborhood Ass'n v. Brown*, -- Fed. Appx. ---, 2013 WL 4517073 (9th Cir. Aug. 27, 2013).

dormant Commerce Clause doctrine – between state and local autonomy, on the one hand, and national economic unity, on the other – is critical to California’s ability to protect its citizens and its environment by regulating commercial activity in the State.

The Attorney General submits this brief primarily to identify and correct the misapplication of law in the briefs of Plaintiffs-Appellants Pharmaceutical Research and Manufacturers of America, *et al.* (“PhRMA”) and their amici. Their arguments, if accepted, would result in an expansion of the doctrine and a corresponding impairment to the ability of state and local governments to carry out their long-standing and traditional responsibilities.

SUMMARY

Alameda’s Ordinance requires pharmaceutical producers that sell or distribute pharmaceuticals in Alameda County to operate and fund “take-back” programs in the County to collect and properly dispose of unwanted and abandoned prescription drugs. *See* ECF No. 28 (“Alameda”) at 5-8 (describing Ordinance in detail). PhRMA argues forcefully that the Ordinance is *per se* unconstitutional, claiming that it directly regulates and discriminates against interstate commerce in violation of the dormant Commerce Clause. As set out below and in Alameda’s brief, it does not.

As the Supreme Court itself has acknowledged, the judge-made law that constitutes dormant Commerce Clause jurisprudence is not always a model of clarity. *See Gen'l Motors Corp. v. Tracy*, 519 U.S. 278, 299 n.12 (1997). In its brief, PhRMA attempts to use this to its advantage.

Advancing a dramatically expansive view of the dormant Commerce Clause, PhRMA conflates terms of art and lines of cases that address distinct types of violations. PhRMA also advocates for unprecedented analytical approaches. PhRMA's arguments are not grounded in existing law, and this Court should decline PhRMA's invitation to expand the scope of the dormant Commerce Clause doctrine.

To counter PhRMA's distortion of the law, this brief begins in Section I with a summary of the dormant Commerce Clause doctrine that briefly explains the three primary, and distinct, ways that state or local laws run afoul of this doctrine – by discriminating against, directly regulating, or unduly burdening interstate commerce. Sections II and III, respectively, refute PhRMA's unsupported attempts to expand the boundaries of what constitutes discrimination and direct regulation. Section IV addresses PhRMA's conflation of “direct burdens” on interstate commerce with “direct regulation” of interstate commerce and demonstrates that PhRMA's interpretation of “direct burdens” is ungrounded and dangerously overbroad.

Lastly, Section V establishes that the Ordinance’s allegedly novel regulatory approach does not, and should not, lend any weight to PhRMA’s arguments that the Ordinance violates the dormant Commerce Clause.

ARGUMENT

I. SUMMARY OF LAW: FRAMEWORK FOR DORMANT COMMERCE CLAUSE ANALYSIS

Under the dormant Commerce Clause, state and local laws that (1) discriminate against interstate commerce; or (2) directly regulate interstate commerce are “virtually *per se* invalid.” *See Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *Dept. of Rev. of Ky. v. Davis*, 553 U.S. 328, 338 (2008) (internal quotation omitted).

Discrimination and direct regulation (also called extraterritorial regulation) are distinct concepts, each with its own lines of cases. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (discussing “cases concerning the extraterritorial effects of state economic regulation”); *Davis*, 553 U.S. at 338-39 (discussing discrimination principles).

Laws that discriminate against interstate commerce are those that protect local economic interests from outside competition. *Davis*, 553 U.S. at 338. Put another way, a law that discriminates is one that “benefit[s] in-state economic interests by burdening out-of-state competitors[.]” *Id.* at 338

(internal quotation omitted). “Most regulations that run afoul of the dormant Commerce Clause do so because of discrimination.” *Nat’l Ass’n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012).

In contrast, laws that directly regulate interstate commerce are quite rare. Laws fit into this narrow category only if they control commerce occurring wholly outside the regulating jurisdiction. *Healy*, 491 U.S. at 336. Because these laws reach into other jurisdictions, they are also referred to as extraterritorial regulations. *See id.*

If a challenged law neither discriminates against interstate commerce nor regulates extraterritorially, courts apply the deferential *Pike* balancing test. *Davis*, 553 U.S. at 338-39 (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)). Under that test, the law survives unless its “burden on interstate commerce clearly exceeds the local benefits.” *Brown-Forman*, 476 U.S. at 579. Laws “frequently survive this *Pike* scrutiny.” *Davis*, 553 U.S. at 339.

II. THIS COURT SHOULD REJECT PhRMA’S ATTEMPTS TO CREATE NEW TESTS FOR, AND NEW FORMS OF, DISCRIMINATION

A. PhRMA Reverses The Accepted Analytical Protocol For Discrimination Analysis

The Supreme Court has established a “protocol for dormant Commerce Clause analysis” in discrimination cases. *Davis*, 553 U.S. at 338. If a

challenged law discriminates by favoring local interests over outside competitors, the law is subject to strict scrutiny. *Id.* at 338. If the law does not discriminate, it is “properly analyzed under the test set forth in *Pike*.” *Id.* at 346. The *Pike* test is expressly “reserved for laws ... with effects upon interstate commerce that are only incidental.” *United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 346 (2007) (internal quotation omitted).

In conflict with this protocol, PhRMA asks this Court to begin its analysis by determining that the Ordinance’s effects on interstate commerce are more than “incidental” – a standard PhRMA does not define. ECF No. 10-1 (“PhRMA”) at 19; *see also id.* at 25, 39. PhRMA argues that the Ordinance’s effects are more than “incidental,” under an unspecified test, and, thus, that the Ordinance is invalid. *Id.* at 19-20; *see also id.* at 25, 39. This is not the proper approach.

Instead, courts must “*first* ask whether [the challenged law] discriminates” against interstate commerce. *United Haulers*, 550 U.S. at 338 (emphasis added). If the law does not discriminate against interstate commerce, its effects are “incidental” as a matter of law and the deferential *Pike* test applies. Contrary to PhRMA’s argument, there is no separate test

to determine whether a law's effects are "incidental" or not. Rather, "incidental" effects are those that result from non-discriminatory laws.

Under PhRMA's unsupported and undefined approach, a law would become subject to strict scrutiny on the grounds that its effects seem too significant to deem "incidental," without a determination that the law discriminates in any way. That would expand the scope of laws subject to strict scrutiny to include any with sizable impacts on interstate commerce. That is not the law, and the Ordinance does not become subject to strict scrutiny simply because PhRMA characterizes its effects as more than "incidental."

This Court should reject PhRMA's invitation to reinvent the analytical protocol and to expand the scope of laws subject to strict scrutiny. The Court should consider, first, whether the Ordinance discriminates – whether it protects local interests by burdening their non-local competitors. As discussed below and in Alameda's brief, the Ordinance does not. *See* Alameda at 32-40. Its effects are, therefore, incidental, and the Ordinance should be subject only to the *Pike* test.⁵

⁵ The Ordinance easily survives the *Pike* test. Its burdens on interstate commerce are slight, and its benefits to public health and the environment are undisputed. *See* Alameda at 57-59.

B. PhRMA Manufactures New Forms Of “Discrimination” That Do Not Involve “Similarly Situated” Competitors

It is undisputed that the Ordinance treats pharmaceutical producers in Alameda *identically* to pharmaceutical producers located outside of Alameda. ER 82-83 at ¶¶ 4-6. Like EPR programs generally, the Ordinance focuses on the waste consequences of the product and on the producer’s responsibility for those consequences, not on the location of the producer. These facts dispose of PhRMA’s discrimination claims, because the Ordinance does not “benefit in-state economic interests by burdening out-of-state competitors.” *Davis*, 553 U.S. at 338.

PhRMA nonetheless argues that the Ordinance discriminates against interstate commerce by favoring local retail pharmacies, local consumers, local taxpayers, and/or local government, over pharmaceutical producers. All of these arguments suffer from the same fatal flaw. Discrimination can only arise when “similarly situated” interests are treated differently, and none of the interests identified by PhRMA are “similarly situated” to pharmaceutical producers. *See Tracy*, 519 U.S. at 298, 310. Indeed, the crux of the “similarly situated” inquiry is whether the entities compete in the same market, and none of the entities identified by PhRMA compete with pharmaceutical producers in any market. *See id.* at 299, 310.

Here, again, PhRMA attempts to distort the test, arguing that retail pharmacies are “similarly situated” to pharmaceutical producers because both purportedly “play a role in” or “benefit economically from” the sale of pharmaceuticals. ECF No. 17-2 (“Foundation”) at 14; PhRMA at 43; *see also* PhRMA at 2, 41 n.7. The Supreme Court has already rejected a virtually identical argument. It found no possibility of discrimination where Maryland differentiated between retail gasoline stations and gasoline producers and regulated the two groups differently. *Exxon Corp. v. Maryland*, 437 U.S. 117, 125 (1978). Alameda may similarly differentiate between pharmaceutical producers and pharmaceutical retailers, by imposing obligations on one but not the other, without discriminating. *See also* Alameda at 34-36.

The Supreme Court has also rejected PhRMA’s contention that imposing costs on out-of-county firms is discriminatory simply because local consumers may benefit.⁶ *See* PhRMA at 42-43. In *PhRMA v. Walsh*, 538 U.S. 644, 670 (2003), the Court held that “rebates paid by out-of-state

⁶ PhRMA’s attempted analogy to *Camps Newfound/Owataonna, Inc. v. Harrison, Me.*, 520 U.S. 564 (1997) is wholly unavailing. *See* PhRMA at 41 n.7; Foundation at 26-27. The law invalidated in that case granted preferential treatment to camps that served Maine residents, making it more attractive to serve them. *Camps*, 520 U.S. at 576. The Ordinance, in contrast, does not make Alameda residents more attractive as customers.

manufacturers and ... used to subsidize sales by local pharmacists to local consumers” were not discriminatory.

PhRMA also claims the Ordinance discriminates against pharmaceutical producers in favor of local taxpayers or local government by shifting the cost of waste disposal from the latter to the former. PhRMA at 38-42; Foundation at 24-25. Neither taxpayers nor local governments compete in any market with pharmaceutical producers. They are not, therefore, “similarly situated,” and any differential treatment of these groups is not discrimination. *See Tracy*, 519 U.S. at 298-99, 310; *see also Alameda* at 34-36.

PhRMA’s argument that taxpayers and governments are “similarly situated” to pharmaceutical producers should also be rejected on the additional ground of judicial restraint. The Supreme Court has recognized that “treating public and private entities the same under the dormant Commerce Clause would lead to unprecedented and unbounded interference by the courts with state and local government.” *United Haulers*, 550 U.S. at 343; *see also id.* at 342 (“Compelling reasons justify treating [laws favoring public entities] differently from law favoring particular *private* businesses over their *competitors*.”) (emphasis added).

Indeed, this “unprecedented and unbounded interference” is precisely what PhRMA seeks here when it asks this Court to invalidate Alameda’s legislative decisions concerning how to operate and fund the disposal of pharmaceutical waste in Alameda. PhRMA would have this Court hold, as a matter of constitutional law, that Alameda County itself must undertake the task and the cost of disposing of pharmaceutical waste and may not ask pharmaceutical producers to do so. PhRMA at 23-25, 28-31, 40-41. But “[t]he dormant Commerce Clause is not a roving license for federal courts to decide what activities are appropriate for state and local government to undertake.” *United Haulers*, 550 U.S. at 343. Specifically, “[i]t is not the office of the Commerce Clause to control the decision of the voters on whether government or the private sector should provide waste management services.” *Id.* at 344.

Taken to their logical extension, PhRMA’s arguments would result in unprecedented scrutiny of, and federal court interference with, a broad range of state and local regulations. Many regulations impose costs and obligations on industries that, at least arguably, *could be* borne by taxpayers or governments instead. For example, the local program upheld in *United Haulers* imposed waste-processing fees on waste haulers, but the government arguably could have imposed equivalent taxes on its citizens

instead. *See id.* at 336. And, instead of “coercing” pharmaceutical producers into negotiating agreements that would provide lower-cost drugs to Maine’s uninsured residents, Maine, arguably, could have asked its taxpayers to fund a low-cost drug program. *See Walsh*, 538 U.S. at 649. Yet, in neither case was it unconstitutional to impose those costs and obligations on commercial entities rather than on taxpayers or the government.

In sum, the dormant Commerce Clause does not require states or local governments to favor business interests over the interests of their taxpayers or the public fisc.⁷ Further, the holding PhRMA seeks here – that a state or local government violates the dormant Commerce Clause simply by asking industry to bear costs that, according to industry, *could be* borne by the public – would do nothing to further the Clause’s central function: the prevention of economic protectionism.

⁷ The taxation cases do not indicate, as PhRMA claims, that regulatory impositions that “reduce local tax burdens” are “forbidden, even if not accompanied by discrimination preferring native companies.” *See* PhRMA at 56-58. These cases, which are irrelevant in this non-tax case, protect outside competitors from being *over*-taxed while recognizing that interstate firms must pay their “just share of [the] state tax burden even though it increases the cost of doing business.” *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274, 279 (1977) (internal quotation omitted).

This Court should reject PhRMA's request to expand the discrimination comparison beyond "similarly situated" competitors.

C. PhRMA Distorts The Case Law Concerning Discriminatory Tariffs And Disruptions To The Flow Of Commerce

In the absence of any discrimination among competing pharmaceutical *producers*, PhRMA argues that the application of the Ordinance to pharmaceutical *products* discriminates against interstate commerce because the pharmaceuticals sold in Alameda arrive there from outside the County. Specifically, PhRMA argues that the application of the Ordinance to these products is akin to a discriminatory tariff and will impermissibly disrupt the flow of commerce. PhRMA at 13, 31-37, 53-57. Neither argument has merit, and both arguments rest on distortions of the law.

As PhRMA notes, a tariff is the "paradigmatic" form of discrimination under the dormant Commerce Clause. PhRMA at 13, 31-37. By definition, a tariff imposes taxes on "goods imported from neighboring States but not [on] similar products produced locally." *Walsh* at 670; *see also Camps*, 520 U.S. at 575. As Alameda establishes, the Ordinance bears no resemblance to a tariff because it treats all products identically, regardless of origin. *See* Alameda at 40. PhRMA argues that the Ordinance is like a tariff because, in "practical effect," the Ordinance applies only to imported goods. PhRMA at

33. This argument is grounded in a misapplication of irrelevant and unrelated terms of art.

PhRMA’s tariff argument relies heavily on the “practical effects” inquiry from *extraterritoriality* cases. *See* PhRMA at 33-36. That inquiry asks whether the challenged law “control[s] conduct *beyond the boundaries of the State.*” *Healy*, 491 U.S. at 336 (emphasis added); *see also S.D. Myers, Inc. v. City & Cnty of San Francisco*, 253 F.3d 461, 467 (9th Cir. 2001) (discussing this Circuit’s application of “practical effect” inquiry in *extraterritoriality* cases). This inquiry is irrelevant to PhRMA’s argument that the Ordinance is a *discriminatory* tariff that burdens the flow of pharmaceuticals *into Alameda*.⁸

Discrimination inquiries, including the test for discriminatory tariffs, are concerned with economic protectionism, not extraterritorial regulation. Thus, when the courts consider “practical effects” in the discrimination context, they are concerned with “*actual* adverse effect[s]” on the relative market shares of local and non-local competitors. *Black Star Farms LLC v. Oliver*, 600 F.3d 1225, 1231 (9th Cir. 2010). These, of course, are not the

⁸ PhRMA’s extraterritoriality arguments are addressed below in Section III, below. *See also Alameda* at 48-51, 53-55.

effects PhRMA claims or can claim, because the Ordinance treats all competing pharmaceutical producers equally.

The Ordinance is nothing like a tariff, and PhRMA's improper blending of irrelevant case law does not demonstrate otherwise.

PhRMA also argues that the application of the Ordinance to products that happen to arrive from outside the County constitutes a discriminatory disruption in the flow of commerce.⁹ PhRMA at 53, 57. Here, again, PhRMA mischaracterizes the law.

As PhRMA's own cases illustrate, laws block the flow of commerce in a discriminatory manner only when they treat products favorably or unfavorably solely on the basis of their origin inside or outside the regulating jurisdiction. *See Chem. Waste Mgmt., Inc. v. Hunt*, 504 U.S. 334, 338-39 (1992) (invalidating Alabama law applying additional fee to waste "generated outside of Alabama"); *Philadelphia v. New Jersey*, 437 U.S. 617, 618 (1978) (invalidating import prohibition against waste "which originated or was collected outside ... the State"); *Hughes v. Oklahoma*, 441 U.S. 322

⁹ As a factual matter, there is no reason to believe the Ordinance will block the flow of pharmaceuticals into Alameda. *See Alameda* at 51-53. Notably, California's EPR programs for pesticide containers and mercury thermostats have been operating since 2009 with no apparent disruption in those markets.

(1979) (invalidating export prohibition for Oklahoma-harvested minnows).

The Ordinance draws no such distinction; all pharmaceuticals, no matter their origin, are treated identically.

Further, the Supreme Court has already rejected PhRMA’s “disruption” argument as a form of discrimination. Where a state’s (or county’s) “entire ... supply flows in interstate commerce,” because there is no intrastate (or intra-county) flow, “claims of disparate treatment between interstate and local commerce would be meritless.” *Exxon*, 437 U.S. at 125. In other words, where, as here, there is no local commerce receiving favorable treatment, a law does not discriminate simply because it applies to goods that arrive via interstate (or inter-county) commerce.

None of PhRMA’s attempts to manufacture discrimination have merit.

III. THIS COURT SHOULD REJECT PHRMA’S ATTEMPT TO EXPAND THE EXTRATERRITORIALITY DOCTRINE

A. Contrary to PhRMA’s Argument, Extraterritoriality Exists Only When The Challenged Law Controls Commerce Occurring Wholly Outside The Regulating Jurisdiction

Extraterritorial regulations – also called “direct regulations” – are those that control commerce taking place entirely in another jurisdiction. *Healy*, 491 U.S. at 336-37. Put another way, laws that control commerce occurring wholly outside the regulating jurisdiction, whether through direct application

or practical effect, are extraterritorial regulations that violate the dormant Commerce Clause. *Id.* The classic example of an extraterritorial regulation is one that controls prices in other jurisdictions.¹⁰ *See id.* at 331-39 (invalidating Connecticut law that controlled beer prices in Massachusetts and discussing other extraterritorial price controls). Similarly, Nevada’s requirement that the National Collegiate Athletic Association (“NCAA”) use Nevada’s procedural rules was extraterritorial, because it would have forced the NCAA “to apply Nevada’s procedures to enforcement proceedings *throughout the country.*” *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993) (emphasis added). The concern in these rare cases is that a state has reached into another sovereign state to regulate commercial activity with no nexus to the regulating state.

PhRMA does not, and cannot, point to any commerce occurring *wholly outside* Alameda that the Ordinance *controls*. It is undisputed that the Ordinance’s regulatory obligations are triggered by sales *in Alameda*. Excerpts of Record (“ER”) p. 83 at ¶¶ 7-8. And the drugs that producers will be obligated to dispose of are also *in Alameda*. *Id.* at ¶ 9. The Ordinance is not an extraterritorial regulation.

¹⁰ Indeed, the Supreme Court has recently indicated that this doctrine should be limited to price control cases. *Walsh*, 538 U.S. at 669.

PhRMA argues that it is sufficient to show that most affected pharmaceutical producers are located outside of Alameda and that the Ordinance imposes affirmative obligations on those producers. *See* PhRMA at 25-26; ECF No. 18-2 (“Chamber”) at 8. It is not. Rejecting a similar extraterritoriality challenge, the Supreme Court upheld Maine’s authority to impose an affirmative obligation to negotiate rebate agreements on “nonresident drug manufacturers,” because the rebates concerned only sales in Maine. *Walsh*, 538 U.S. at 654, 669.

PhRMA also suggests that it is sufficient to show that pharmaceuticals arrive in Alameda as part of a larger chain of commerce that extends beyond the County’s borders, or that, as PhRMA claims, Alameda is reaching “up” that chain to regulate producers. *See* PhRMA at 25-26; Chamber 8, 11-14. Again, it is not. In *Clover Leaf*, Minnesota permissibly imposed milk packaging requirements “up” a complex chain of commerce that involved raw material providers, container manufacturers, dairies, and retailers, many of whom were out-of-state. *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 458 n.1, 472-73 (1981). Minnesota did so, in part, to address waste disposal concerns in its state. *Id.* at 458. Despite effects “up” the chain of commerce that extended into other states, Minnesota could regulate

its own milk market to address local waste disposal concerns.¹¹ Alameda may, therefore, regulate its own pharmaceutical market regardless of similar effects. The key question is whether the state (or county) is regulating transactions in *another* jurisdiction's market, as neither Minnesota's law did nor Alameda's Ordinance does.

In sum, Alameda cannot control the sale of pharmaceuticals in other counties or states, any more than Connecticut could control the price of beer sales in Massachusetts, *Healy*, 491 U.S. at 337-38, or Nevada could dictate the rules for enforcement proceedings throughout the country, *NCAA*, 10 F.3d at 639. Alameda has not attempted to do so. Alameda is well within the bounds of the Constitution in requiring pharmaceutical producers to take responsibility for the waste consequences of the products they sell *in the County*, as the Ordinance does.

B. PhRMA's Analytical Framework For Extraterritoriality Is Unprecedented

Unable to point to any commerce occurring wholly outside Alameda that the Ordinance controls, PhRMA advances a new and entirely unsupported analytical approach to extraterritoriality, much as it did with

¹¹ Indeed, there was never a question that these effects were extraterritorial and *per se* violative of the Clause. Rather, the Court analyzed these effects under the deferential *Pike* test. *Id.* at 476.

discrimination. *See, supra*, Sec. II.A. In PhRMA’s view, the first step in this inquiry is whether the Ordinance is a legitimate exercise of Alameda’s police power.¹² PhRMA at 23-24. If, PhRMA argues, the Ordinance does not implicate Alameda’s police power, then it must be a direct regulation of interstate commerce because its burdens fall on interstate companies. *Id.* at 23-28. The analysis PhRMA advances here is not the law, as the discussion above demonstrates. The “critical inquiry” in extraterritorial cases is “whether the practical effect of the regulation is to control conduct beyond the boundaries of the [County].” *Healy*, 491 U.S. at 336. The approach PhRMA advocates has no bearing on this central question.¹³ This Court should reject PhRMA’s unsupported approach.

IV. THIS COURT SHOULD REJECT PhRMA’S CONFLATION OF “DIRECT BURDENS” ON INTERSTATE COMMERCE AND “DIRECT REGULATIONS” OF OUT-OF-STATE COMMERCE

In another attempt to alter the doctrine to suit its purposes, PhRMA uses the terms “directly burden” and “directly regulate” interchangeably, suggesting that placing a burden on interstate commerce is the same as

¹² In its brief, Alameda has fully countered PhRMA’s premise – that the Ordinance is not an exercise of the County’s police power. *See* Alameda at 30-32.

¹³ Underscoring that this approach to *extraterritoriality* has no basis in the applicable law, PhRMA relies on *discrimination* and *Pike* cases, *see* PhRMA at 22-24, or provides no citations at all, PhRMA at 25-27.

regulating commerce in another jurisdiction. *See, e.g.*, PhRMA at 20 (describing these phrases as “equivalent[.]”). Indeed, PhRMA argues that both phrases are implicated whenever a state or local regulation imposes any obligations on firms located outside the regulating jurisdiction. PhRMA at 13-15, 23-28, 30-32, 36-39. In fact, these phrases have distinct meanings as a matter of both plain language and dormant Commerce Clause jurisprudence, and neither phrase applies here.¹⁴

As discussed in Section III above, “direct regulations” are those that reach extraterritorially into other jurisdictions to control commerce with no nexus to the regulating jurisdiction. *See Healy*, 491 U.S. at 336. While the precise meaning of the term “direct burden” is less clear, because it is infrequently used and rarely applied,¹⁵ it is clear that “direct burdens” are related to discrimination, not extraterritoriality. Notably, the Supreme Court’s decision in the seminal “direct burden” case “hinged upon the fact that the ‘primary’ purpose of the regulation was to inhibit competition.”

¹⁴ PhRMA claims its combination of “direct regulations” and “direct burdens” comes from this Court’s *NCAA* decision. PhRMA at 19. But, as an extraterritoriality case, *NCAA* properly discusses only “direct regulation.” *NCAA*, 10 F.3d at 638-40.

¹⁵ This discussion omits taxation cases, both because those represent a separate, and inapplicable, line of cases and because the Supreme Court has rejected the distinction between “direct” and “indirect” burdens in those cases. *Quill Corp. v. North Dakota*, 504 U.S. 298, 309-10 (1992).

Kleenwell Biohazard Waste & Gen'l Ecology Consultants, Inc. v. Nelson, 48 F.3d 391, 397 n.7 (9th Cir. 1995) (describing *Buck v. Kuykendall*, 267 U.S. 307 (1925)); *see also Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27, 39, 44 (1980) (finding statute “directly burdens interstate commerce” because it made “the out-of-state location [of a firm] an explicit barrier” to entry). “Direct burdens,” then, are similar to many discriminatory laws in that they are “intended to prohibit competition.” *Kleenwell*, 48 F.3d at 395. Indeed, this Court has indicated that “direct burdens” may be a form of discrimination. *See Pac. Merchant Shipping Ass’n v. Goldstene*, 639 F.3d 1154, 1177 (9th Cir. 2011) (describing category of regulations “that directly burden interstate commerce *or otherwise discriminate* against out-of-state interests”) (emphasis added). “Direct burdens,” thus, bear no resemblance to, and have no connection with, “direct regulations” that control commerce occurring wholly in another jurisdiction.

This Court should reject PhRMA’s conflation of these two distinct concepts and PhRMA’s resulting, expansive interpretation of a “direct burden” on interstate commerce as practically any imposition of costs or

obligations on entities located outside the County.¹⁶ PhRMA at 28-31. This Court has already rejected one “expansive interpretation” of “direct burden” because a broad interpretation would invalidate “virtually any regulation of local markets.” *Kleenwell*, 48 F.3d at 396. This Court should reject PhRMA’s expansive interpretation for precisely the same reason.

V. THIS COURT SHOULD REJECT PhRMA’S SUGGESTION THAT NOVEL REGULATORY APPROACHES ARE SUSPECT UNDER THE DORMANT COMMERCE CLAUSE

PhRMA repeatedly describes the Ordinance as “unprecedented” or as “a ‘first in the nation’” law, suggesting that the purported novelty of a regulatory approach is relevant to the dormant Commerce Clause analysis.¹⁷ PhRMA at 11, 25, 38; Foundation at 2; Chamber at 6. It is not. For example, the Supreme Court gave no weight to the “allegedly unique” nature of Maine’s pharmaceutical rebate program when assessing its constitutionality under the Clause. *See Walsh*, 538 U.S. at 662, 669-70; *see also PhRMA v. Concannon*, 249 F.3d 66, 80 (1st Cir. 2001) (referring to that same program as a “novel legislative approach”). Indeed, if novel regulatory

¹⁶ This Court should also reject PhRMA’s “direct burden” argument because PhRMA has not, and cannot, show that the Ordinance’s purpose is to inhibit competition. *See Alameda* at 30-32, 41, 52.

¹⁷ As explained above, EPR programs are not, in fact, “unprecedented.” *See supra* pp. 2-3.

approaches made laws more vulnerable to challenge, “the role of the States as laboratories” of regulatory innovation would be substantially chilled. *See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). Such a view of the law could have serious, adverse effects on California, which has repeatedly been recognized as an important leader and regulatory innovator. *See, e.g., Motor & Equip. Mfrs. Ass’n, Inc. v. EPA*, 627 F.2d 1095, 1109-1111 (D.C. Cir. 1979). The Court should reject PhRMA’s attempt to introduce a new, and harmful, factor into the analysis.

CONCLUSION

For the foregoing reasons, and consistent with existing dormant Commerce Clause precedent, the Attorney General respectfully urges this Court to affirm the district court’s grant of summary judgment to Alameda.

Dated: January 22, 2014

Respectfully submitted,

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**CERTIFICATE OF COMPLIANCE
PURSUANT TO FED.R.APP.P 32(a)(7)(C) AND CIRCUIT RULE 32-1**

I certify that: (check (x) appropriate option(s))

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January 22, 2014

Dated

/s/ M. Elaine Meckenstock

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RULE 29 STATEMENTS

This brief of *amicus curiae* is submitted under Federal Rule of Appellate Procedure 29(a), and all parties have consented to its filing.

Pursuant to Federal Rule of Appellate Procedure 29(c)(5), Attorney General Kamala D. Harris states that: (1) no party's counsel authored this brief in whole or in part; (2) no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and (3) no person other than *amicus curiae*, its members or its counsel contributed money that was intended to fund preparing or submitting the brief.

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT
Case No. 13-16833

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed Brief of Amicus Curiae Attorney General Kamala D. Harris In Support of Appellees with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit on January 22, 2014 using the CM/ECF system. All case participants will be served electronically by the CM/ECF system.

/s/ M. Elaine Meckenstock
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